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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|------------|------------|-------------------------------|---------------------|------------------|
| 10/618,868 | 07/14/2003 | | Bjorn M. Nilsson | 13425-056002 | 6954 |
| 26161 | 7590 | 05/02/2005 | | EXAMINER | |
| FISH & RIC | | ON PC | BALASUBRAMANIAN, VENKATARAMAN | | |
| BOSTON, M | | 0 | | ART UNIT | PAPER NUMBER |
| • | | | | 1624 | |

DATE MAILED: 05/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | A 1. 1. A. | A 11 4/-> | | | | |
|---|--|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| 0.00 | 10/618,868 | NILSSON, BJORN M. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Venkataraman Balasubramanian | 1624 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | _• | | | | | |
| · | action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | nce except for formal matters, pro | secution as to the merits is | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 3 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-25 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) <u>1-25</u> are subject to restriction and/or e | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | r. | | | | | |
| |)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the | drawing(s) be held in abeyance. See | 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correct | on is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. & 119(a) | -(d) or (f) | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents | s have been received in Application | on No | | | | |
| Copies of the certified copies of the prior | ity documents have been receive | d in this National Stage | | | | |
| application from the International Bureau | | | | | | |
| * See the attached detailed Office action for a list | of the certified copies not receive | d. | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal Pa | te atent Application (PTO-152) | | | | |
| Paper No(s)/Mail Date | 6) Other: | | | | | |
| | | | | | | |

DETAILED ACTION

Claims 1-25 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 4-25 are drawn to compound of formula I shown in claim 1 wherein Y and Z both nitrogen and X is CH, namely pyrimidine compound, composition and method of use, classified in class 544, subclasses 301, 303, 309, 323 etc., class 514, subclasses 256, 269, 272, 274, 275 depending upon the choice of substituents in the pyrimidine ring.
- II. Claims 1-3, 5-8 and 10-25 are drawn to compound of formula shown in claim 1 wherein X is CH or C-CF₃, Z is CH and Y is nitrogen, namely pyridine compound, composition and method of use classified in class 546, subclass 193, 268.1, class 514, subclasses 317, 336, class 544, subclass 252.13 etc. depending upon the choice of substituents in the pyridine ring.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core namely pyrimidino versus isomeric pyridines or piperazine or piperidone depending upon the choice of R₁ and R₂. Consequently, the groups have different classifications and require separate prior art searches. They can be made and used independently. Art, which may render obvious or anticipate one of the groups would not necessarily do the same for the other

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group as evidenced by the references cited in the Information Disclosure Statement.

Each can support a patent, as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Furthermore, it is mandatory to classify and search the entire heterocyclic cores that are controlling and with limited available per case, it would be a serious search burden to search all these heterocyclic cores.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: pyrimidine, and pyridine or piperazine or piperidine species. See claim 9.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1-8 and 10-25 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephonic restriction requirement request to Jeffery His and Cathy McCardri on 4/12/2005 did not result in an election as the application has been transferred to another attorney. Hence, upon further consideration, and in view of distinct nature of each invention, the restriction is set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

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Any inquiry concerning this communication from the examiner should be

addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571)

272-0662. The examiner can normally be reached on Monday through Thursday from

8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is

Mukund Shah whose telephone number is (571) 272-0674. If Applicants are unable to

reach Mukund Shah within 24-hour period, they may contact James O. Wilson, Acting-

SPE of art unit 1624 at 571-272-0661.

The fax phone number for the organization where this application or proceeding

is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of

this application or proceeding should be directed to the receptionist whose telephone

number is (571) 272-1600.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAG. Status

information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-2 17-9197 (toll-free).

Verhataraman Balasubramanian

4/24/2005